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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,262	03/25/2002	Alessandro Seneci	TRUF101	2926
21658	7590	03/23/2004	EXAMINER	
DYKAS, SHAVER & NIPPER, LLP			OH, SIMON J	
P.O. BOX 877			ART UNIT	
802 WEST BANNOCK STREET, SUITE 405			PAPER NUMBER	
BOISE, ID 83701			1615	

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/089,262

**Applicant(s)**

SENECI ET AL.

**Examiner**

Simon J. Oh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Papers Received***

Receipt is acknowledged of the applicant's amendment and response, both received on 07 January 2004.

### ***Claim Rejections - 35 USC § 112***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 9 and 17 under 35 U.S.C. 112, second paragraph is maintained.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

By the ranges of the amounts of the components recited in Claim 10, the examiner reads this composition defined by this claim to contain at least 20% by weight of excipients and/or adjuvants. However, it is the opinion of the examiner that the presence of any excipient or adjuvant conflicts with the limitation set forth in Claim 1, which recites the at least one hydrogenated fatty acid as the only vehicle. Here, it is the position of the examiner that the term "vehicle" is a broad generic term that does not specifically exclude excipients or adjuvants from its definition. Thus, the subject matter of this claim has been rendered indefinite.

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***Response to Arguments for Claim Rejections under 35 USC § 112***

Applicant's arguments filed 07 January 2004 have been fully considered but they are not persuasive.

As previously set forth, Claims 9 and 17 both depend upon Claim 6, which in turn depend, in part, upon Claim 5. Claims 9 and 17 are defined to contain only active principles and hydrogenated fatty acids. However, this is not consistent with the scope of Claim 5, which requires the additional presence of excipients. This inconsistency of scope renders Claims 9 and 17 indefinite. As this rejection has remained un-addressed by the applicant, the examiner must maintain the rejection of record under 35 U.S.C. § 112.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Okada *et al.* is maintained.

***Response to Arguments for Claim Rejections under 35 USC § 103***

Applicant's arguments filed 07 January 2004 have been fully considered but they are not persuasive.

Although the applicant has amended the claim to further define it apart from the prior art, it is the position of the examiner that the current amendment is not sufficient to overcome the

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prior art rejections of record. Although the compositions of the prior art are disclosed to contain vehicles other than hydrogenated fatty acids, the prior art must be read with a broad, reasonable interpretation. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

Specifically, it is upon the applicant to show through the submission of conclusive evidence that the presence of the additional vehicles, as disclosed in the prior art, would be detrimental to its function. Furthermore, upon review of the specification, the examiner cannot find a portion that defines the term “vehicle” in such a way as to include only hydrogenated fatty acids and exclude the standard excipients and adjuvants as listed therein. As such, the examiner considers the term “vehicle” to include hydrogenated fatty acids as well as excipients and adjuvants. The examiner notes that such excipients and adjuvants include artificial materials such as PVP, and so the examiner must question the criticality of how an embodiment that includes only active ingredients and hydrogenated fatty acids provide a patentably distinct advantage over the compositions of the prior art, particularly in their function of delivering active ingredients to patient in need thereof.

Concerning the applicant’s arguments regarding the modification of the disclosure of the prior art, the examiner would like to clarify and point out that the issue is not modification. Rather, it is the examiner’s position that the selection of granulating hole sizes and cooling temperature ranges would be well within the range of knowledge of one of ordinary skill in the art. Unless the applicant can demonstrate through the submission of evidence that the selection of such parameters would be unknown or unobvious to one of ordinary skill in the art or that it

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produces unexpected results, the examiner finds it obvious in view of the broad disclosure of the prior art.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Simon J. Oh  
Examiner  
Art Unit 1615

sj0

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SUPERVISORY PATENT EXAMINER  
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